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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,177	11/15/2000	Glen H. Erikson	E1047/20048	3217

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

25

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,177

Applicant(s)

ERIKSON ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 24) filed on June 2, 2003 has been entered.
2. Claims 1-63 are pending.
3. This application is filed on November 15, 2000 and claims priority to US Patent application Nos. 09/664,827, filed on September 19, 2000, 09/613,263, filed on July 10, 2000, and 09/468,679, filed on December 21, 1999.

Response to Arguments

3. Applicant's response to the office action (Paper No.8) is fully considered and is found persuasive.
4. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a) over Eckhart et al. in view of Deng et al., applicants amendment and arguments have been considered but are moot in view of the new ground(s) of rejection.
5. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a) over Eckhart et al. in view of Erikson et al., applicants amendment to the specification claiming priority to the Patent of Erikson et al. and the arguments are considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over George Jr. (USPN. 5,451,502) in view of McGavin et al. (J. Mol. Graphics, Vol. 7, pages 218-232, 1989).

George Jr. teaches a catalytic hybridization composition (kit) of claim 1 (see column 4, lines 48-50) and method for assaying binding of claim 24 (see column 3, lines 49-67, column 4, lines 1-35) wherein the method comprises

(a) providing a probe or oligonucleotide containing at least a nucleobase sequence and a scissile linkage (see column 3, lines 49-58);

(b) providing an enzyme adapted to cleave said at least one scissile linkage sequence (see column 3, lines 59-61);

(c) providing a target containing at least one target nucleobase sequence (see column 3, lines 49-61, column 4, lines 19-28);

(d) combining said probe, said enzyme and said target in a hybridization medium (see column 3, lines 62), which contains water, a buffer, and at least one promoter (label) and incubating the reaction mixture to hybridize (see column 13, lines 38-59, column 4, lines 24-28);

(e) cleaving hybridized probes at said at least one scissile linkage to provide unbound probe fragments and detecting said unbound probe fragments to assay binding between said probe and said target (see column 3, lines 63-65, column 4, lines 15-17).

With regard to claims 25-26, George Jr. teaches that the method was carried out at temperatures ranging from 2-60⁰ C and pH of the hybridization buffer of about 5 to about 9 (see column 8, lines 34-53, column 10, lines 4-22, column 11, lines 65-68, column 12, lines 1-61);

With regard to claims 27-28, 30-34, George Jr. teaches a flurophore label tethered to a probe with detectable marker using an atom, an inorganic radical (comprise monovalent cation), heavy metal (transition metals) (divalent or valency grater than 1) (see column 6, lines 25-46);

With regard to claim 36, George Jr. teaches that the incubation time is not more than 24 hours (see column 10, lines 23-30, column 12, lines 50-61);

With regard to claims 37-40, George Jr. teaches that the method comprises detecting probe-target hybrid using change in fluorescence, chemiluminescence signal comprising rodhamine and fluorescein (see column 7, lines 1-19);

With regard to claims 41-44, George Jr. teaches that the method comprises energy transfer labels, the signal generated by the labels could be detected as an indication of hybridization of probe with a target (see column 7, lines 8-19);

With reference to claims 53-55, George Jr. teaches said enzyme cleaves only nucleobases having predetermined backbone characteristics (see column 5, lines 29-37);

With regard to claim 56, George Jr. teaches said probe contains at least one interspersed sequence (column 5, lines 41-46);

With regard to claims 62-63, George Jr. teaches said probe comprises an electrical circuit or optically active reporter group adapted to emit a detectable signal (see column 6, lines 25-68).

With regard to claims 2-6, George Jr. teaches at least a portion of the multiplex (target-probe complex) comprises synthetic sequence (probe) or structure (see column 6, lines 20-24), probe and target could be single or double stranded (see column 5, lines 38-68, column 6, lines 1-24); at least a portion of the probe comprises mRNA or cDNA sequences (see column 6, lines 1-24);

With regard to claim 15, 23, George Jr. teaches that the probe comprises 5-57 nucleotides and target contains unlimited number of bases (see column 6, lines 1-24, column 9, lines 11-23);

With regard to claim 16-18, George Jr. teaches that the target could include genomic DNA or PCR product (cDNA) (see column 5, lines 47-68);

With regard to claim 19-22, George Jr. teaches that the multiplex structure (probe-target complex) could be bound to a solid support and solid support is electrically conductive (see column 7, lines 35-49).

However George Jr. did not specifically teach that the multiplex structure (probe-target complex) is bond solely through Watson-Crick base triplets.

With regard to claims 1-63, McGavin et al. teach a multiplex structure using computer graphics wherein McGavin et al. disclose three-strand and four-stranded structure formation solely through Watson-Crick pairing in which Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in

continuous and specific contact (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3, page 230, column 1, paragraphs 1-3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and composition of DNA multiplex complex as taught by George Jr. with the inclusion of Watson-Crick base pairing forming model as taught by McGavin et al. in order to obtain the invention as a whole. An ordinary artisan would have motivated to have added the structural stability of Watson-Crick base pairing of nucleic acid strands in a multiplex structure to the method of George Jr., because McGavin et al. taught Watson-Crick kind of base pairing as a strong specific interaction between complementary strands and its growing significance in genetic recombination or specificity of interaction between strands. Therefore an ordinary artisan would have recognized the expected benefits of stability of Watson-Crick kind of base pairing structures and would have motivated to add the limitation to the method and composition of binding assay as taught by George Jr to obtain a more stable multiplex structure.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications

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and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
October 27, 2003



JEFFREY FREDMAN
PRIMARY EXAMINER